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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,649	02/16/2006	Giorgio Terenghi	TEPH109	4566

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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,649	TERENGHI ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-14* is/are pending in the application.

4a) Of the above claim(s) *7-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The final office action mailed on July 23, 2007 is hereby vacated and is substituted with the following action.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed on May 4, 2007 is acknowledged. Claim 2 is cancelled. Claim 1 is amended. Claims 1 and 3-14 are pending in this application. Claims 7-14 are withdrawn with traverse (filed on 12/4/06) from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Dec 4, 2006.

2. Claims 1 and 3-6 are under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

4. Applicant's arguments filed on May 4, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Objections

5. Claim 3 is objected to because of the following informalities: claim 3 depends from claim 2, which has been canceled. The claim has been interpreted as depending from claim 1. Appropriate correction is required.

Claim Rejections/Objections Withdrawn

6. The rejection of claims 1 and 3-6 under 35 U.S.C. 112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is withdrawn in response to Applicants' arguments.

Claim Rejections Maintained

In view of the amendment filed on May 4, 2007, the following rejections remain.

Obviousness-Type Non-Statutory Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-6 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-34 of U.S. Patent No. 6610764, claims 1-4 and 6-28 of US 6838493, claims 1-3 and 5-20 of US 6548569, claims 1-4

and 6-30 of US 6867247, claims 30 and 35-61 of US 7179883, for the reasons made of record in the office action mailed on 2/21/07, and as set forth below.

Claims 1 and 3-6 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 and 21-25 of copending Application No. 10/835926 (US2004/0234576, which has a common assignee), and claims 1-8 of copending Application No. 11/193580 (US2006/0058470, which has a common assignee), for the reasons made of record in the office action mailed on 2/21/07, and as follows.

Since U.S. Patent No. 6610764, US 6838493, US 6548569, US 6867247, US 7179883 and copending Application Nos. 10/835926 (US2004/0234576) and 11/193580 (US2006/0058470) share a similar specification, the reasons of the rejection and citation are based on the reference of US6548569, which are also applied to all the cited references (i.e. issued patents and copending applications).

At p. 5 of the response, Applicants argue that the prior art does not disclose the claimed nerve conduit made of 4-hydroxybutyrate polymers in a form of a tube or sheet and having the pore size between 5-500μm in diameter. Applicants' arguments have been fully considered but they are not persuasive.

In contrast to Applicant assertion, the issued patents and copending applications teach a biocompatible polyhydroxyalkanoate composition, or a device or a polymeric filament or fiber for a medical device comprising 4-hydroxybutyrate polymers for different medical uses including nerve regeneration. Although the claims do not recite the shape and size, the specification teaches a biodegradable device "comprising" a

polyhydroxyalkanoate polymer comprising 4-hydroxybutyrate in a form of porous conduit such as a commercial conduit from the products of NEUROTUBE™ as described by the '569 patent (see col. 16, lines 42-52, in particular), which is reasonably in the form of a tube as recited in instant claim 1. In addition, although the claims do not specify the conduit with a pore size between 5-500μm in diameter, the specification of the cited references teaches a process of generation of a conduit with a pore size between nanometer-500μm in diameter using pore forming agents or particles with diameters between nanometers to 500 microns (μm), and also generation of a pore size between 80-180μm for nerve conduits by using sodium chloride crystals, which are particles with diameters between 80-180μm (see for example, col. 33, line 40; col. 37, line 36 of the '569 patent). For example, the specification of the '569 patent teaches that the pore size of PHA is between nanometers to 500μm in diameter by using pore forming agents or particles with diameters between nanometers to 500 microns (i.e. as it relates to instant claims 4-5; see col. 10, lines 31-42 as in the '569 patent). The '569 patent also teaches a process of forming a pore size between 80-180μm for a nerve conduit made of P4HB using pore forming agents or particles (sodium chloride crystals) with diameters between 80-180μm (see col.33, example 4; col. 37, example 6).

"In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)", See MPEP 2144.05-I.

In addition, note that the intended use for nerve regeneration is not given patentable weight since the composition of the issued patents and copending

applications is the same composition as recited in instant claims 1 and 3-6. Thus, the issued patents and the claimed device of the instant application claim an invention substantially overlapping in scope since the range of the different pore size in the instant conduit is an obvious variant and can have the same results in nerve regeneration.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hadlock et al. (WO 01/54593,published on Aug 2, 2001) in view of Martin et al. (2003. 16: 97-105 cited in the previous office action), for the reasons made of record in the office action mailed on 2/21/07, and as follows.

At p. 5 of the response, Applicant argues that the prior art does not make obvious over the claimed nerve conduit made of 4-hydroxybutyrate polymers in a form of a tube or sheet and having pores between 5-500μm in diameter. Applicants' arguments have been fully considered but they are not persuasive.

In contrast to Applicant assertion, the claimed conduit is obvious over the applied references. The applied references teach a nerve conduit made of P4HB in a form of a tube or sheet with a pore size between10-100 μm or between180-240μm in diameter because Hadlock (WO 01/54593) (Hadlock (WO'593)) teaches a porous nerve regeneration conduit "comprising" biodegradable polymers of polyhydroxyalkanoate, polyhydroxybutyric acid or polyesters with a pore size between 10-100 μm (i.e. as it relates to instant claim 1; see p.3; p. 7, 2nd paragraph; p. 14, claims 6-8) and Martin et al. teach P4HB patches (i.e. sheet) with a pore size between 180-240μm (as it relates to instant claims 4-5;see p. 100, 1st col. 2nd paragraph) and P4HB is more stable and useful for tissue engineering (i.e. including nerve regeneration). In addition, as previously made of record, Hadlock (WO'593) also teaches the conduit comprising Schwann cells (i.e. neural cells) or neurotrophic agents and the thickness of the conduit is between 5-200μm (as it relates to instant claims 1 and 3-6; see p.2-4). Although Hadlock (WO'593) does not teach 4-hydroxybutyrate per se, Martin et al. teaches poly-4-hydroxybutyrate (P4HB) (i.e. a polymer) is polyester that belongs to the class of polyhydroxyalkanoate (PHA) (i.e. comprises 4-hydroxybutyrate) and for use in tissue regeneration; i.e. including nerve regeneration (see p.97, 1st col. 1st paragraph; 2nd col. 1st paragraph, in particular). Thus, it would have been obvious to a skilled artisan at the

time the instant invention was made to use 4-hydroxybutyrate polymers to substitute 3-hydroxybutyrate to make or improve a nerve conduit and have expected success since 4-hydroxybutyrate polymers (P4HB) are more stable and are useful for tissue engineering, such as nerve regeneration, and the pore size between180-240μm is within the ranges as recited in instant claims. Since the P4HB conduits with a narrower and a broader range of pore size from the prior art have the same results in promoting nerve regeneration, the limitation of "between 5-500 μm" in the instant claims would predictably result in the same effects on nerve regeneration as in the prior art.

"In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)", See MPEP 2144.05-I.

At p. 5 of the response, Applicant argues that the claimed conduits have an unexpectedly and significantly greater rate of nerve regeneration as compared to the prior art using 3-hydroxybutyrate or other polymeric nerve conduits (i.e. 1mm/day vs. 1mm/week, also see p.4 of the response). Applicant's arguments have been fully considered but they are not persuasive.

In response, use of P4HB to substitute P3HB to make or improve nerve conduits of Hadlock (WO'593) is obvious to a skilled artisan at the time the invention was made because the results of nerve regeneration using a nerve conduit made of P3HB are known and the results of substituting P3HB with P4HB in a nerve conduit of Hadlock (WO'593) are also expected because Hadlock (WO'593) teaches a nerve regeneration conduit "comprising" biodegradable polymers of polyhydroxyalkanoate,

polyhydroxybutyric acid or polyesters and Martin et al. teach that P4HB is more stable and useful for tissue engineering (i.e. including nerve regeneration) and also teaches P4HB patches (i.e. sheet) with a pore size of 180-240μm (i.e. as it relates to instant claims 4-5;see p. 100, 1st col. 2nd paragraph).

"The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co.v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)" see MPEP§ 2144.07.

Note that

"Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967). See MPEP 716.02(c)-II.

In addition,

"To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960)." See MPEP 716.02(d)-II

Applicants allegedly argues that the claimed conduits have unexpected results over the prior art. In contrast, Applicant fails to provide evidence of side-by-side comparisons to demonstrate unexpected results as claimed. No comparative data shows the unexpected results derived from a conduit made of P4HB in a shape and limitation as recited in instant claim 1 versus those of the combined reference teachings. No data demonstrates the unexpected results from different pore size versus a given pore size in the examples described within the specification. Further, no data demonstrates a given structure of two sets of devices (instant vs. prior art) in a physical dimension would generate unexpected results as claimed.

"Evidence of unexpected results must be weighed against evidence supporting *prima facie* obviousness in making a final determination of the obviousness of the claimed invention. *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978)." See MPEP 716.02(c)-I.

Since Applicant fails to provide any evidence as discussed above to support any unexpected results as claimed, the claimed conduit is obvious over the prior art, absent evidence to the contrary.

New Grounds of Rejection Necessitated by the Amendment

The following rejections are new grounds of rejections necessitated by the amendment filed on May 5, 2007

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3-6 are indefinite because Applicants recite “suitable” in the claim 1. Claims 3-6 are indefinite as depending from indefinite claim 1. The term "suitable” in claim 1 is a relative term, which renders the claim indefinite. The term " suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant fails to set forth the metes and bounds of what is encompassed within the definition of “suitable”. Since the metes and bounds are not

unknown, a skilled artisan cannot contemplate what would be considered as suitable for nerve repair as recited in the claim. Thus the claims are indefinite.

Claim Rejections - 35 USC § 103

10. Claims1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US Patent No. 6548569, issued on Apr 15, 2003, priority date Mar 25, 1999) in view of Seckel (US. Patent No. 5584885, issued on Dec 17, 1996) and evidentiary references Schlossauer. (Neurosurgery, 2006. 59:740-748) and Clavijo-Alvarez et al. (Plast. Reconstr. Surg. 2007. 119:1839-1851).

Claims 1 and 3-6 are drawn to a nerve regeneration device comprising a polyhydroxyalkanoate polymer comprising 4- hydroxybutyrate (P4HB) in the form of a porous conduit tube or sheet and having a diameter of between 5 and 500 microns (μm).

US Patent No. 6548569 ('569 patent) teaches devices of tissue regeneration or nerve guidance/regeneration made of biocompatible polyhydroxyalkanoates (PHA) comprising poly-4-hydroxybutyrate (P4HB) as recited in instant claims 1 and 3 (see col. 4, lines 20-57; col.7, lines 31-35, in particular). The '569 patent teaches a biodegradable device comprising a polyhydroxyalkanoate polymer comprising 4-hydroxybutyrate as a preferred embodiment (see col.7, lines 31-33, in particular) in a form of porous conduit such as having the shape of the nerve conduit products of NEUROTUBE™ as incorporated by the references including US Patent NOs. 5735863, 5584885 and 5026381 (see col. 16, lines 42-52). The '569 patent teaches that the pore size of PHA is

between nanometers to 500μm in diameter by using pore forming agents or particles with diameters between nanometers to 500 microns (i.e. as it relates to instant claims 4-5; see col. 10, lines 31-42, in particular). The '569 patent also teaches the process of forming pore size of 80-180μm for nerve conduits made of P4HB using pore forming agents or particles (sodium chloride crystals) with diameters between 80-180μm (see col.33, example 4; col. 37, example 6).

In addition, US Patent No. 5584885 (i.e. one of the incorporated references in the '569 patent) teaches nerve guides (i.e. nerve conduits) comprising Schwann cells, growth factors and drugs as recited in instant claim 6 (see col.7, lines18-col.8, lines 29; col. 16, lines 22-60, in particular).

The size of nerve conduits of NEUROTUBE™ is a tube with 2-8mm in diameter and 4cm in length and having the pore size of 30-50μm in diameter, which is within the limitation recited in instant claim 1, as evidenced by Schlosshauer (see p. 742, table 2, Schlossauer. Neurosurgery, 2006. 59:740-748) and Clavijo-Alvarez et al. (see p. 1840, 3rd paragraph; Clavijo-Alvarez et al. Plast. Reconstr. Surg. 2007. 119:1839-1851).

Although the '569 patent does not teach the pore size between 5μm-500μm diameter, the range of pore size recited in the instant claims is obvious over the '569 patent because the claimed ranges (i.e. 5-500μm) overlap or lie inside ranges disclosed by the prior art (i.e. nanometer-500μm).

"In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)", See MPEP 2144.05-I.

In addition, the '569 patent shows that both of the conduits having the pore size with the ranges between nanometer-500μm and 80-180μm in diameter are effective in promoting nerve regeneration. Since both of the conduits with a broader range and a narrower range of the pore size have the same effects on nerve regeneration, the recitation of the pore size between 5μm-500μm in the instant claims is an obvious variant because the results from the claimed conduits with the claimed pore size would predictably have the same result in nerve regeneration as in the prior art.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105USPQ 233, 235 (CCPA 1955)" See MPEP 2144.05-II.

11. Claims 1 and 3-6 are rejected under 35 U.S.C. 103 (a) as being unpatentable over U.S. Patent No. 6610764 (issued on Aug 26, 2003, priority date Nov 17, 1997), US 6838493 (issued on Jan 4, 2005, priority date Mar 25, 1999), US 6867247 (issued Mar 15, 2005, priority date Mar 25,1999), US 7179883 (issued on May 19, 2005, priority date Mar 25, 1999), US2002/0156150 (US Application No. 10/082954, published Oct 24, 2002) or US2002/017358 (US Application No. 10/136499, published Nov 21, 2002) each in view of Seckel (US. Patent No. 5584885, issued on Dec 17, 1996) and evidentiary references Schlossauer. (Neurosurgery, 2006. 59:740-748) and Clavijo-Alvarez et al. (Plast. Reconstr. Surg. 2007. 119:1839-1851). The reasons of the rejection are as set forth above at paragraph 10 and in the section of double patenting at paragraph 7 since these cited references share the same specification with that of US 6548569.

The issued patents US 6610764, US 6838493, US 6867247, US 7179883 and copending applications US2002/0156150 (US Application No. 10/082954) and US2002/017358 (US Application No. 10/136499) teach a biocompatible polyhydroxyalkanoate composition, or a device or a polymeric filament or fiber for a medical device comprising 4-hydroxybutyrate polymers for different medical uses including nerve regeneration. These specifications teach a biodegradable device comprising a polyhydroxyalkanoate comprising 4-hydroxybutyrate in a form of porous conduit such as having the shape of the nerve conduit products of NEUROTUBE™ as incorporated by the references and having the pore size of PHA between nanometers to 500μm or 80-180μm in diameter, which is within the range of a pore size of 5-500μm in diameter in the form of a tube as recited in instant claims 1 and 3-5. US Patent No. 5584885 (i.e. one of the incorporated references) teaches nerve guides (i.e. nerve conduits) comprising Schwann cells, growth factors and drugs as recited in instant claim 6 (see col.7, lines18-col.8, lines 29; col. 16, lines 22-60, in particular). The size of nerve conduits of NEUROTUBE™ is a tube with 2-8mm in diameter and 4cm in length and having the pore size of 30-50μm in diameter, which is within the limitation recited in instant claim 1, as evidenced by Schlosshauer (see p. 742, table 2, Schlossauer. Neurosurgery, 2006. 59:740-748) and Clavijo-Alvarez et al. (see p. 1840, 3rd paragraph; Clavijo-Alvarez et al. Plast. Reconstr. Surg. 2007. 119:1839-1851). Thus, the claimed conduit is obvious over the prior art.

Conclusion

12. NO CLAIM IS ALLOWED.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

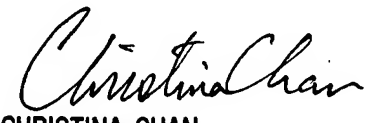
Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-

4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (571) 272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
October 18, 2007



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